K121577

JUN 22 2012

510(k) – SUMMARY OF SAFETY AND EFFECTIVNESS

In accordance with 21 CFR 807.92, the following summary of the information is provided.

1. **Submitter's Name:**
   Toshiba America Medical Systems, Inc.
2. **Address:**
   2441 Michelle Drive
   Tustin, CA 92780-2068
3. **Establishment Registration:**
   2020563
4. **Contact Person:**
   Charlemagne Chua
   Manager Regulatory Affairs
   (714) 730-5000
5. **Submission Date**
   May 30, 2012 (revised June 20, 2012)
6. **Device Proprietary Name:**
   APLIO ARTIDA MODEL SSH-880CV V3.0
7. **Common Name:**
   Diagnostic Ultrasound System
8. **Classification:**
   Regulatory Class: II
   Review Category: Tier II
   Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [CFR 892.1550]
   Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [CFR 892.1560]
   Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [CFR 892.1570]
9. **Predicate Devices:**
   Toshiba APLIO ARTIDA MODEL SSH-880CV Ultrasound Diagnostic System, K090158
10. **Device Description:**
    The APLIO ARTIDA SSH-880CV is a mobile Ultrasound Diagnostic System for cardiology and vascular imaging. It has a capability of providing a 3D real time image of a heart as well as 2D images. The system is consists of a main console, a color LCD display and several transducers. The compatible transducers are linear array, curved linear and phased array with a frequency range of 2.5 MHz to 7.5MHz. Accordingly it has various software options for cardiac and vascular examinations.

11. **Summary of Intended Uses:**

The intended use of this system is to visualize structures, characteristics, and dynamic processes within the human body using ultrasound and to provide image information for diagnosis for cardiac and vascular.

12. **Technological characteristics:**

The APLIO ARTIDA SSH-880CV V3.0 (subject device) employs the same scientific technology as the APLIO ARTIDA SSH-880CV V2.0 (predicate device).

13. **New Feature**

Activation Imaging (AI) – 3D Wall Motion Tracking (3D WMT), cleared by K090158, is a software to analyze the movement of the myocardium from the acquired 3D images. The Activation Imaging (AI) is added as a new feature of the 3D WMT. This is one of the strain display mode with a color coding depending on the arrival time to the defined strain value. And the color remains over after the arrival of the defined strain value.

14. **Determination of Substantial Equivalence:**

Toshiba Medical Systems Corporation believes that the APLIO ARTIDA SSH-880CV V3.0 is substantially equivalent to APLIO ARTIDA SSH-880CV V2.0.

15. **Safety:**

This device is designed and manufactured under the Quality System Regulations as outlined under 21 CFR§820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37 and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

16. **Summary of Testing**

a. **Bench Tests**

Testing was conducted utilizing phantoms and accepted image quality metrics.

b. **Clinical Test**

A clinical evaluation of Activation Imaging (AI) was conducted at a evaluation site for the validation of AI.

i. Subjects – Adult male and female, ages 18 and above, scheduled for routine Echocardiographic Evaluation by their physician and with dyssynchrony.

ii. Study endpoints – The primary endpoint was the collection of images from 10 subjects. A pass/fail criterion was used to determine if the AI images provided the activation timing.

iii. Adverse Events – There were no adverse events during the course for the clinical evaluation.

iv. Results – The result of the clinical evaluation satisfied a pass criterion.

c. **Discussion**

The predicate device is Aplio Artida SSH-880CV V2.0. The changes from V2.0 to this device are the addition of 6 transducers (PVT-375BT, PET-510MB, PST-25BT, PLT-704AT, PET-508MA and PET-512MC) and the addition of the Activation Imaging (AI) to the wall motion tracking. The addition of the transducers does not change the intended use range of this device. The addition of Activation Imaging feature to the 3D Wall Motion Tracking will allow the display of wall motion information of the myocardium with the use of color coding. This does not change the effectiveness and the safety of the device.

17. Conclusion:

New feature that is being added to the Aplio Artida SSH-880CV V3.0 do not change the indication for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to this modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 22 2012

Toshiba Medical Systems Corporation, Japan
% Ms. Charlemagne Chua
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K121577
Trade/Device Name: Aplio Artida™ (SSH-880CV), v3.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 29, 2012
Received: May 30, 2012

Dear Ms. Chua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio Artida™ (SSH-880CV), v3.0, as described in your premarket notification:

Transducer Model Number

PST-25SX
PST-30BT
PTS-30SBT
PST-50BT
PST-65AT
PLT-704SBT
PC-20M
PST-25BT
PVT-375BT
PLT-704AT
PET-508MA
PET-510MB
PET-512MC

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): _____

Device Name: Aplio Artida™ (SSH-880CV), v3.0

Indications for Use:

The DIAGNOSTIC ULTRASOUND SYSTEM APLIO ARTIDA (Model SSH-880CV) is intended to be used for the following types of studies: cardiac, transesophageal, abdominal and peripheral vascular.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K121577

System: SSH-880CV
Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	P	P	P	P	P	P	
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	P	P	P	P			
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)	P	P	P		P	P	P	P	P			
Musculo-skeletal (**Superficial**)	P	P	P		P	P	P	P	P			
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	P	P
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	P	P
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	P	P			P		
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P	P	P	P	P	P	P			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510k of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K k121577

System: SSH-880CV
Transducer: PST-25SX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult	P						P					P
Cardiac Pediatric	P						P					P
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121577

System: SSH-880CV
Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	P	P	P	P	P	P	
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	P	
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121577

System: SSH-880CV
Transducer: PST-30SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	P	P			P	P	
Cardiac Pediatric	P	P	P	P	P	P	P			P	P	
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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510K K121577

System: SSH-880CV
Transducer: PST-50BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	P	P			P		
Cardiac Pediatric	P	P	P	P	P	P	P			P		
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121577

System: SSH-880CV
Transducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	P	P			P		
Cardiac Pediatric	P	P	P	P	P	P	P			P		
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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Previous 510(k) of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121577

System: SSH-880CV
Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	P	P	P	P			
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)	P	P	P		P	P	P	P	P			
Musculo-skeletal (**Superficial**)	P	P	P		P	P	P	P	P			
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	P	P	P	P			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121577

System: SSH-880CV
Transducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult				P								
Cardiac Pediatric				P								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				P								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer:K090158

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121577

System: SSH-880CV
Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult	E	E	E	E	E	E	E			E	E	
Cardiac Pediatric	E	E	E	E	E	E	E			E	E	
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121577

System: SSH-880CV
Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal	E	E	E		E	E	E	E	E			
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	E	E	E		E	E	E	E	E			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121577

System: SSH-880CV
Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	E	E	E		E	E	E	E	E			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121577

System: SSH-880CV
Transducer: PET-508MA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	E	E	E	E	E	E	E			E		
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121577

System: SSH-880CV
Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	E	E	E	E	E	E	E			E		
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121577

System: SSH-880CV
Transducer: PET-512MC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	E	E	E	E	E	E	E			E		
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K103629

*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

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510K K121577